Supreme Court, U.S.
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No. 98 198

IN THE
SUPREME COURT OF THE UNITED STATES
OCTOBER TERM, 1997

JOSEPH F. WHELAN, ET AL.,
PETITIONERS

v.

MERRELL DOW PHARMACEUTICALS INC.,
RESPONDENT.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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40 pp

QUESTIONS PRESENTED

1. Whether the district court violated the standards of Daubert v. Merrell Dow Pharmaceuticals Inc., 509 U.S. 579 (1993), when it dismissed the case, even though plaintiffs had set forth four peer-reviewed studies which were statistically significant and relevant to the issue of causation.

2. Whether Daubert permits a holding by the lower federal court that there is no causation of birth defects as a matter of law when there are four peer-reviewed, admissible studies which show a statistically significant relationship concerning causation of the birth defects at issue.

PARTIES TO THE PROCEEDING

Petitioners, the plaintiffs below, are Joseph F. Whelan, and his parents, F. Joseph Whelan, M.D., and Elizabeth A. Palmer. Respondent, the defendant below, is Merrell Dow Pharmaceuticals Inc.

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IN THE

SUPREME COURT OF THE UNITED STATES

OCTOBER TERM, 1997

No.

JOSEPH F. WHELAN, ET AL.,

PETITIONERS

v.

MERRELL DOW PHARMACEUTICALS INC.,

RESPONDENT.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Joseph F. Whelan, et al., petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the District of Columbia Circuit in this case.

OPINIONS BELOW

The orders of the court of appeals (App., infra, 1a-2a; 14a-16a) are not reported. The opinions of the district court (App., infra, 3a-13a) are not reported.

JURISDICTION

The judgment of the court of appeals was entered on March 11, 1998. A petition for rehearing was denied on April 30, 1998. App., infra, 14a. The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

STATEMENT

1. Joseph F. Whelan suffered birth defects following his mother's ingestion of Bendectin during pregnancy. The birth defects suffered included pyloric stenosis, cleft palate and ventricular septal defect (a heart defect). Joseph Whelan did not suffer limb defects.

2. Joseph F. Whelan and his parents

filed suit in 1983 against Merrell Dow Pharmaceuticals, Inc., alleging that his mother's ingestion of Bendectin caused his birth defects. It is not necessary to set out the entire proceedings of this protracted litigation. The case was returned to the District of Columbia after pretrial proceedings in the multidistrict litigation in the Sixth Circuit.

3. By a show cause order dated October 21, 1988 (App., infra, 12a - 13a), the district court ordered plaintiffs to identify evidence to be used to satisfy their burden on the causation issue. Plaintiffs then identified four published epidemiological studies, which are:

a. P. Aselton, H. Jick, S. Chentow, D. Perera, J. Hunter and K. Rothman, "Pyloric Stenosis and Maternal Bendectin Exposure." 120 AMERICAN JOURNAL OF EPIDEMIOLOGY 251 (1984);

b. B. Eskanazi, M. Bracken, "Bendectin (Debendox) as a risk factor for pyloric stenosis," 144 AM. J. OBSTET. GYNECOL. 919 (December 15, 1982);

c. J. Golding, S. Vivian, J. Baldwin, "Maternal Anti-nauseants and Clefts of Lip and Palate," 2 HUMAN TOXICOLOGY 63 (1983);

d. K. Rothman, D. Fyler, A. Goldblatt, M. Kriedberg, "Exogenous hormones and other drug exposures of children with congenital heart disease," 109 AMER. J. EPIDEMIOLOGY 433 (1979).

The plaintiffs identified these four published studies in Plaintiff's Response to the Order to Show Cause, filed on July 24, 1989. These studies should be deemed admitted, because they were included in Defendant's First Request for Admissions, filed on July 11, 1986.

4. These published studies indicate a statistically significant relationship between the ingestion of Bendectin and the types of defects suffered by Joseph Whelan. For example, the Aselton/Jick study showed a relative risk of 7.6 for women who filled five or more prescriptions during their pregnancy. The Eskanazi/Bracken study had an odds ratio of 4.33. This study is identified

in Turpin v. Merrell Dow Pharmaceuticals, Inc., 959 F.2d 1349, 1353 n. 1 (6th Cir. 1992), as having a statistically significant confidence interval which would show a greater likelihood that the suspected agent did cause the defect. The Golding study states that the relative risk of clefts of lip and palate with Bendectin use was 2.88. Finally, the Rothman study shows that the relative risk for congenital heart defects was 1.8.

5. In a memorandum order dated August 30, 1990 (App., infra, 5a -11a), the district court ordered the case be dismissed. It found that plaintiffs had not shown good cause why the case should not be dismissed pursuant to the precedent of Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C.Cir.), cert. denied, 493 U.S. 882 (1989); and Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159 (D.C.Cir.), cert. denied, 498 U.S. 950 (1990).

Even though plaintiffs had identified these four published studies, the trial court simply ignored them.

The memorandum order stated that plaintiffs were required to show admissible scientific evidence and that plaintiffs had not made the requisite showing. (App., infra, 11a). This finding was clearly erroneous, because plaintiffs had proffered four published epidemiological studies. The trial court made no gatekeeping decision about those four studies.

The dismissal by the district court was premised upon a show cause motion. There was no summary judgment motion filed and there was no trial.

6. In a memorandum order dated September 9, 1997 (App., infra, 3a-4a), the district court denied plaintiff's motion, which was filed on September 18, 1990, to vacate the August 29, 1990, memorandum order. The district court found that plaintiffs had not shown that there had been an intervening change in controlling law. The district court did not cite or refer to the intervening 1993 decision of this Court, Daubert v. Merrell Dow, 509 U.S. 579 (1993).

The district court again clearly

erred in its finding that plaintiffs had identified no specific scientific evidence upon which they would rely at trial. App. infra, 3a.

The four published epidemiological studies were identified yet again by plaintiffs in their Reply to defendant's Opposition to Plaintiffs' Motion to Vacate Order, filed on October 9, 1990. Even though plaintiffs had identified scientific evidence, the trial court avoided its gatekeeping responsibilities under Daubert by ignoring those four published studies. Instead of addressing the studies in light of the Daubert factors, the district court erred by finding erroneously that plaintiffs had offered no specific scientific evidence. The district court failed to comply with this Court's mandate set out in Daubert.

7. In an order dated March 11, 1998 (App., infra, 1a-2a), a panel of the court of appeals granted Merrell Dow's motion for summary affirmance. The court of appeals found that, even if the evidence produced by appellants

were admissible, no reasonable jury could have found it sufficient to establish causation. In granting the motion for summary affirmance, the court of appeals relied upon Raynor v. Merrell Pharmaceuticals Inc., 104 F.3d 1371, 1376-77 (D.C.Cir. 1997). The court of appeals failed, as had the district court, to cite, refer to or address this Court's precedent in Daubert.

8. The plaintiffs' petition for rehearing and suggestion for rehearing in banc were denied by orders dated April 30, 1998. App., infra, 14a-16a.

REASONS FOR GRANTING THE PETITION

In affirming the dismissal of the case in spite of plaintiffs' proffer of four admissible, peer-reviewed epidemiological studies showing causation, the District of Columbia Circuit violated the holding in Daubert about admissibility of evidence. This Court found in Daubert that:

> Its overarching subject [the inquiry about admissibility] is the scientific validity - and thus the evidentiary relevance and reliability - of the principles that underlie a proposed submission. The focus, of course, must be solely on principles and methodology, not on the conclusions that they generate.

Daubert, 509 U.S. at 594-95.

The holding in this case by the lower courts was based on the insufficiency of the evidence of causation as a matter of law. That holding is in direct conflict with Daubert, which emphasized that the focus must be on methodology and not on conclusions. It also conflicts with numerous other Bendectin decisions, which were based on the inadmissibility of different types of evidence, such as animal studies.

In this case, the plaintiffs set forth four peer-reviewed epidemiological studies to support causation. In the

face of this proffer, their case was dismissed. Review is warranted to resolve this circuit conflict and to ensure that the courts cannot eviscerate Daubert by simply ignoring admissible evidence or summarily finding it to be insufficient as a matter of law.

1. The court of appeals erred in holding that no reasonable jury could have found the evidence sufficient to establish causation. The court found the evidence insufficient as a matter of law, without identifying the evidence at issue or addressing the admissibility of the four studies. It must be emphasized that the plaintiffs proffered four peer-reviewed, epidemiological studies, of the type considered admissible by the tests suggested in Daubert.

2. The factors identified in Daubert as relevant to determining whether the evidence constitutes scientific knowledge include: (1) whether the technique can be and has been tested; (2) whether the technique "has been subjected to peer review and

publication;" (3) "the known or potential rate of error;" (4) "the existence and maintenance of standards controlling the technique's operation;" and (5) whether the technique has attained general acceptance within the relevant scientific community. Id. at 593-94.

These factors have been relied upon by the circuits in determining admissibility. See, e.g., Maryland Cas. Co. v. Therm-O-Disc, Inc., 137 F.3d 780, 785 n. 29 (4th Cir. 1998); Summers v. Missouri Pacific R.R. System, 132 F.3d 599, 603 n. 4 (10th Cir. 1997); United States v. Gilliard, 133 F.3d 809, 812 (11th Cir. 1998).

3. The evidence relied upon in the other Bendectin cases involved animal-cell studies, live-animal studies, chemical-structure analyses, and recalculations of epidemiological data. Daubert, 509 U.S. at 2792. See also Richardson, 857 F.2d at 826; Lynch v. Merrell-National Laboratories, 830 F.2d 1190, 1194-96 (1st Cir. 1987); DeLuca v. Merrell Dow Pharmaceuticals, Inc., 911 F.2d 941, 943 (3rd Cir. 1990); Brock

v. Merrell Dow Pharmaceuticals, Inc., 874 F.2d 307, 312, mod., 884 F.2d 166, reh'g denied, 884 F.2d 167 (5th Cir.), cert. denied, 494 U.S. 1040 (1990); Turpin, 959 F.2d at 1358-60; Elkins v. Richardson-Merrell, Inc., 8 F.3d 1068, 1070 (6th Cir. 1993).

The similarity of the evidence (in vitro studies, in vivo studies, and reanalyses of human epidemiological studies) in those cases has been noted in several circuits. See Elkins, 8 F.3d at 1070 (proof in this case is identical to proof offered in two other Bendectin cases in this circuit); Raynor, 104 F.3d at 1374 (this court held that similar evidence in Richardson was inadmissible).

This case involving Joseph Whelan is starkly different, because the proffered evidence consists of four published epidemiological studies. The studies in this case are not the in vitro and in vivo studies, nor the recalculations of data, which have widely been criticized and found inadmissible.

As such, this evidence is enhanced

by qualifying under the publication factor identified by this Court in Daubert, 509 U.S. at 593-94. Moreover, on remand in Daubert, Judge Kozinski of the Ninth Circuit emphasized the significance of publication. He explained that the acceptance of research for publication, after it has been subjected to peer review, indicates that the research is taken seriously by other scientists and meets at least the minimum criteria of good science. Daubert v. Merrell Dow Pharmaceuticals, Inc., 43 F.3d 1311, 1318 (9th Cir. 1995).

This case did not rely upon the in vitro studies, in vivo studies, and reanalyses of human epidemiological studies which were found inadmissible or insufficient in the cases noted above. In view of the factors cited by this Court in Daubert, the District of Columbia Circuit erred in finding that there was insufficient evidence as a matter of law to prove causation.

4. The stark contrast between this case and the Bendectin cases discussed above derives from the

difference in the birth defects at issue. The cases above concerned limb defects. It must be emphasized that Joseph Whelan did not suffer limb defects. As a result, any holding about causation of limb defects by ingestion of Bendectin is not binding on the causation issue in this case.

The perception of the much-publicized and much-litigated Bendectin controversy is that the studies show that Bendectin does not cause birth defects. In fact, there is verbiage to that effect in the case law. However, a careful analysis of the holdings makes it apparent that the causation findings that are so generally perceived as definitive concerned limb defects. See, e.g., Richardson, 857 F.2d at 831 (Dr. Done admitted that no published work found an association between Bendectin and limb reduction defects); Ealy, 897 F.2d at 1159 (no epidemiological study has found a statistically significant association between Bendectin and limb reduction defects); Brock, 884 F.2d at 167 (the

Brocks failed to present statistically significant epidemiological proof that Bendectin causes limb reduction defects); Lynch, 830 F.2d at 1194 (irrelevance of Bendectin to the incidence of limb defects has been demonstrated); DeLuca, 911 F.2d at 945 (null hypothesis is that there is no association between Bendectin exposure and an increase in limb reduction defects).

The holding of the D.C. Circuit that causation in insufficient as a matter of law is plainly in conflict with Daubert, which stated that the focus must not be on the conclusions generated. Id. at 595. Moreover, the holdings about other types of studies (which are not published epidemiological studies) about a different type of birth defect cannot support any finding about lack of causation as a matter of law.

Review is warranted so this Court can provide further development on the considerations of the evaluation and use of scientific evidence about causation. As Chief Justice Rehnquist noted, judges do not need to become

amateur scientists to perform the gatekeeping responsibility. Daubert, 509 U.S. at 2800 (Rehnquist, C.J., concurring in part and dissenting in part).

Chief Judge Mayer of the Federal Circuit expressed a similar sentiment, describing his "knowledge" of anodization from his undergraduate studies and a dictionary in his chambers, while acknowledging that he is not an expert in the field. Fromson v. Anitec Printing Plates, Inc., 132 F.3d 1437, 1448 (Fed.Cir. 1998)(Mayer, C.J., concurring).

By contrast, without identifying the evidence at issue in this case or addressing its scientific validity or its acceptance within the scientific community, the District of Columbia Circuit asserted that no reasonable jury could have found that evidence sufficient to establish causation. This holding is in conflict with Daubert and is not supported by the circuit precedents based on inadmissibility of animal and other unpublished studies.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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July 29, 1998

APPENDIX A

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 97-7174

JOSEPH F. WHELAN, ET AL.,
Appellants

v.

MERRELL DOW PHARMACEUTICALS INC.,
Appellee.

Before: Williams, Sentelle, and Henderson, Circuit Judges.

[Filed March 11, 1998]

ORDER

Upon consideration of the motion for summary affirmance, the response thereto, and the reply, it is

ORDERED that the motion for summary affirmance be granted. The merits of the parties' positions are so clear as to warrant summary action. See Taxpayers Watchdog, Inc. v. Stanley, 819 F.2d 294, 297 (D.C.Cir. 1987)(per curiam); Walker v. Washington, 627 F.2d 541, 545 (D.C.Cir.)(per curiam), cert. denied, 449 U.S. 994 (1980). Even if the evidence produced by appellants in support of their claim were admissible, no reasonable jury could have found it sufficient to establish causation. See Raynor v. Merrell Pharmaceuticals Inc., 104 F.3d 1371, 1376-77 (D.C.Cir. 1997).

The Clerk is directed to withhold issuance of the mandate herein until seven days after disposition of any timely petition for rehearing. See D.C. Cir. Rule 41.

Per Curiam

APPENDIX B

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CA No. 83-3108 (NHJ)

JOSEPH F. WHELAN, ET AL.,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Defendant.

September 9, 1997

MEMORANDUM ORDER

Plaintiffs Joseph Whelan and his parents allege that Joseph's birth defects resulted from his mother's ingestion during pregnancy of Bendectin, a prescription drug manufactured by defendant. On October 21, 1988, the Court issued a Show Cause Order requiring plaintiffs to "identify specific, admissible expert evidence they would adduce at trial and that would satisfy their burden on the causation issue in this case, under the requirements of Richardson v. Richardson-Merrell Inc., 857 F.2d 823 (D.C.Cir. 1988). In response, plaintiffs asserted that Richardson was not binding and identified no specific scientific evidence upon which they would rely at trial. On

August 29, 1990, the Court concluded that plaintiffs had not shown good cause why the case should not be dismissed pursuant to Richardson and dismissed the civil action. Presently before the Court is the motion of plaintiffs to vacate the Court's August 29, 1990, Memorandum Order.

Having reviewed the motion, the Court concludes that plaintiffs have not shown that there has been an intervening change in controlling law, previously unavailable evidence, or a need to correct a clear legal error or manifest injustice. See e.g., Raynor v. Merrell Pharmaceuticals Inc., 104 F.3d 1371, 1376 (D.C.Cir. 1997). Accordingly, it is this 9th day of September 1997,

ORDERED that the motion to vacate the Memorandum Order dismissing this case [#125] be, and hereby is, denied.

/s/ Norma Holloway Johnson
Chief United States
District Judge

APPENDIX C

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CA No. 83-3108

JOSEPH F. WHELAN, ET AL.,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Defendant.

August 30, 1990

MEMORANDUM ORDER

Plaintiffs Joseph F. Whelan and his parents, Dr. Francis J. Whelan and Elizabeth A. DeGarza, allege that Joseph's birth defects were caused by his mother's ingestion of Bendectin, a prescription drug manufactured by the defendant. This case was stayed by the Court's May 20, 1987, Order, granting plaintiffs' motion to await the decision of the United States Court of Appeals for the District of Columbia in a similar action.

In Richardson v. Richardson-Merrell, Inc., 857 F.2d 823 (D.C.Cir. 1988), cert. denied, 110 S.Ct. 218 (1989), the Court of Appeals affirmed a judgment notwithstanding the verdict in favor

of Merrell Dow (sued under its former name, Richardson-Merrell, Inc.), finding that the expert opinion of plaintiff's witness was inadmissible. Richardson's holding, that an expert opinion that Bendectin is a human teratogen which causes birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of a "wealth of published epidemiological data" to the contrary, 857 F.2d at 832, was held binding in Ealy v. Richardson-Merrell, Inc., 897 F.2d 1159, 1660 (D.C.Cir. 1990).

In Richardson plaintiff's expert witness, Dr. Alan Done, opined that Bendectin is a human teratogen. Dr. Done predicated his opinion on four types of data. After reviewing the probative value of each type, the court concluded:

> These three types of studies then -- chemical, in vitro, and in vivo - cannot furnish a sufficient foundation for a conclusion that Bendectin caused the birth defects at issue in this case. Studies of this kind, singly or in combination, are not capable of proving causation in human beings in the face of the overwhelming body of contradictory epidemiological evidence. Perhaps mindful of this, the last type of evidence considered by Dr. Done consisted of the epidemiological studies. When such studies are available and relevant, and particularly when they are numerous and span a significant period of

> time, they assume a very important role in determinations of questions of causation.

Richardson, 857 F.2d at 830. Although no published epidemiological study had concluded that there is a statistically significant association between Bendectin and the type of birth defects at issue in Richardson, Dr. Done claimed to have obtained a statistically significant result by recalculating the data. As the court observed, "the studies rejected by Dr. Done had been published in peer-reviewed scientific journals, while Dr. Done has neither published his recalculations nor offered them for peer review." Id. at 831.

In light of the Court of Appeals' decision, Merrell Dow filed a motion to lift the stay of this action and for a show cause order. On October 21, 1988, the Court granted Merrell Dow's motion and issued an Order requiring plaintiff's to identify specific, admissible expert evidence that they would adduce at trial and that would satisfy their burden on the causation issue pursuant to Richardson. Plaintiffs asserted in a November 4, 1988, response that Richardson was not binding on this Court and that the show cause Order was void. Treating plaintiff's response as a motion to vacate the Order to show cause, the Court denied the motion by Order dated June 27, 1989, and granted plaintiffs additional time to comply. Plaintiffs filed their response on July 24, 1989, in large part repeating arguments that the Court rejected in its Order of June

27, 1989. Plaintiffs have also filed response dated May 11, 990, to defendant's April 3, 1990, Notice of Filing.

Plaintiffs responses to the show cause Order and defendant's Notice of Filing make essentially three arguments: (1) that they disagree with the holdings of Richardson and Ealy regarding the veracity of non-epidemiological studies; (2) that they satisfy the legal requirements of Richardson and Ealy because they do not plan to use the same expert witnesses who testified in those cases; and (3) that Richardson and Ealy are inapposite because both decisions involved limb defects whereas this case involves other types of birth defects.

Plaintiffs' response fails to show good cause as to why this case should not be dismissed pursuant to Richardson and Ealy.

First, despite plaintiff's protestations to the contrary, this Court is bound by the holdings in Richardson and Ealy. This Circuit has found, as a matter of law, that expert opinion testimony, which relies upon chemical structure analysis, in vivo studies, in vitro studies, or reformulated epidemiological data, is not admissible. Expert testimony in a Bendectin case, any Bendectin case, cannot be presented to a jury unless supported by some other type of scientific evidence. The burden is on plaintiffs to demonstrate that they will be able to supply the jury with expert testimony that would be acceptable to the Richardson court. Plaintiffs

have not done so, but rather, sought to have this Court chart a new path from that directed by the Court of Appeals. This the Court refuses to do.

Second, the holdings of Richardson and Ealy are not limited to the specific experts that testified in those cases. Plaintiffs' suggestion that it should be allowed to proceed to trial simply because it has different experts strains credulity. In Richardson, the Court of Appeals carefully took pains to note that it had reviewed the record, including the wealth of published reports on Bendectin, and that no credible and admissible scientific evidence exists that would establish the drug as a human teratogen. It was the type of evidence not the expert whose testimony was found wanting in Richardson. Indeed, the Ealy court specifically rejected the testimony of one expert who had not testified in Richardson. The Ealy court rejected the idea that Richardson should not apply simply because a different expert or different testimony was offered. This Court would be loath to narrow the holdings of Richardson or Ealy to operate merely as a bar against the testimony of the specific individual experts testifying in those cases without the most express direction from the Court of Appeals that that was exactly what it intended.

Third, there is nothing implicit or explicit that restricts the holding of Richardson and Ealy solely to limb defects.[1] Both cases discuss more

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1 Richardson is grounded in the

broadly the question of whether Bendectin is a human teratogen. Plaintiffs' argument cannot be squared with either the language or holdings of those decisions. Assuming arguendo that there is some merit to this

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fact that Bendectin "... has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic." Richardson, 857 F.2d at 832. It as this feature of the case that led the Court of Appeals to look beyond the mere conclusions of experts. The Richardson court, distinguished itself from Ferebee v. Chevron Chemical Co., 736 F.2d 1529 (D.C.Cir. 1984), cert. denied, 469 U.S. 1062. Plaintiff's experts in Ferebee expressed the opinion that paraquat, a defoliant, had caused a fatal lung disease contracted by an agricultural worker, even though they acknowledged such an event was rare. The Ferebee court denied defendant's motion for judgment notwithstanding the verdict, noting" "[j]udges ... have no special competence to resolve the complex and refractory causal issues raised by the attempt to link low level exposure to toxic chemicals with human disease. On questions such as these, which stand at the frontier of current medical and epidemiological inquiry, if experts are willing to testify that such a link exists, it is for the jury to decide whether to credit such testimony." Ferebee 736 F.2d at 1534 (emphasis added). The holding of Richardson is narrow in the sense that

contention, it would still be incumbent upon plaintiffs to demonstrate pursuant to Richardson and Ealy admissible scientific evidence upon which a jury could reasonably conclude that Bendectin causes Joseph's birth defects. Plaintiffs have not made the requisite showing and, therefore, may not proceed.

Upon careful consideration of the entire record, the Court concludes that plaintiffs have not shown good cause as to why this action should not be dismissed pursuant to Richardson and Ealy.

Accordingly, it is this 29th day of August, 1990,

ORDERED that plaintiffs' case be and hereby is, dismissed with prejudice.

/s/ Norma Holloway Johnson
United States
District Judge

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it applies only to those cases within the "frontiers of science," although it limited the approach adopted in Ferebee to only those cases involving novel issues of causation. Plaintiffs have not made any showing, other than the naked allegation, that Joseph's birth defects render inapposite the studies considered by the Richardson and Ealy courts or that the state of knowledge with respect to the potential for Bendectin to have caused the specific maladies affecting Joseph is at the frontiers of science. Richardson thus controls this case.

APPENDIX D

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

CA No. 83-3108

JOSEPH F. WHELAN, ET AL.,
Plaintiffs,

v.

MERRELL DOW PHARMACEUTICALS, INC.,
Defendant.

October 21, 1988

ORDER

Upon consideration of the motion of defendant Merrell Dow Pharmaceuticals Inc. to lift stay and to show cause, the memorandum of points and authorities in support thereof, and the record herein, it is this 21st day of October, 1988,

ORDERED that the motion of defendant to lift the stay imposed by the Court in Order dated May 20, 1987, be and hereby is, granted; it is further

ORDERED that defendant's motion to show cause be, and hereby is, granted; and it is further

ORDERED that within fifteen (15) days of the date of this Order plaintiffs identify specific, admissible expert

evidence that they would adduce at trial and that would satisfy their burden on the causation issue in this case, under the requirements of Richardson v. Richardson-Merrell Inc., No. 87-7023 (D.C. Cir. Sept. 27, 1988).

/s/ Norma Holloway Johnson
United States
District Judge

APPENDIX E

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 97-7174

JOSEPH F. WHELAN, ET AL.,
Appellants

v.

MERRELL DOW PHARMACEUTICALS INC.,
Appellee.

Before: Williams, Sentelle, and Henderson, Circuit Judges.

[Filed April 30, 1998]

ORDER

Upon consideration of appellants' petition for rehearing filed April 8, 1998, it is

ORDERED that the petition be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

/s/ BY: Robert A. Bonner
Deputy Clerk

APPENDIX F

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 97-7174

JOSEPH F. WHELAN, ET AL.,
Appellants

v.

MERRELL DOW PHARMACEUTICALS INC.,
Appellee.

Before: Edwards, Chief Judge; Wald, Silberman, Williams, Ginsburg, Sentelle, Henderson, Randolph, Rogers, Tatel and Garland, Circuit Judges.

[Filed April 30, 1998]

ORDER

Upon consideration of appellants' Suggestion for Rehearing In Banc, and the absence of a request by any member of the court for a vote, it is,

ORDERED that the suggestion be denied.

Per Curiam

FOR THE COURT:
Mark J. Langer, Clerk

/s/ BY: Robert A. Bonner
Deputy Clerk

Circuit Judge Tatel did not participate in this matter.

(2)

No. 98-198

FILED
AUG 31 1998
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IN THE
Supreme Court of the United States
OCTOBER TERM, 1998

JOSEPH F. WHELAN, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF IN OPPOSITION

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WILSON - EPES PRINTING CO., INC. - 789-0096 - WASHINGTON, D.C. 20001

QUESTION PRESENTED

Whether this Court should review the decision of the District of Columbia Circuit summarily affirming the dismissal of petitioners' claims that Bendectin caused Joseph F. Whelan's birth defects, when that decision is consistent with this Court's decision in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993), and the final decisions of every federal appellate court that has considered a Bendectin case, which have held either that plaintiffs' Bendectin evidence is inadmissible or insufficient to prove that Bendectin causes birth defects?

RULE 29.6 STATEMENT

As to parent corporations, respondent Merrell Pharmaceuticals Inc. (which is sued in this case under its former name, Merrell Dow Pharmaceuticals Inc.) is a wholly-owned subsidiary of Hoechst Marion Roussel Inc. The two stockholders of Hoechst Marion Roussel, Inc. are HMR Pharma, Inc. and Hoechst Marion Roussel, S.A. HMR Pharma, Inc. is wholly owned by Hoechst Marion Roussel AG, which in turn is a wholly-owned subsidiary of Hoechst AG. Hoechst AG wholly owns Hoechst Celanese Corporation and Hoechst Corporation. Hoechst Corporation wholly owns HCCP Acquisition Corporation, which owns 52.94% of Copley Pharmaceuticals Inc.

Merrell Pharmaceuticals Inc. has three nonwholly-owned foreign subsidiaries in which stock could be publicly available: Marion Merrell S.A. (Spain), Gruppo Lepetit S.p.A. (Italy), and Marion Merrell S.A. (France).

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IN THE

Supreme Court of the United States

OCTOBER TERM, 1998

No. 98-198

JOSEPH F. WHELAN, *et al.*,
Petitioners,

v.

MERRELL DOW PHARMACEUTICALS INC.,
Respondent.

On Petition for a Writ of Certiorari to the United States Court of Appeals for the District of Columbia Circuit

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BRIEF IN OPPOSITION

Respondent Merrell Dow Pharmaceuticals Inc. ("Merrell") respectfully requests that this Court deny the Petition for a Writ of Certiorari seeking review of the decision of the United States Court of Appeals for the District of Columbia Circuit in this case.

COUNTERSTATEMENT

1. In this case, which was filed in 1983, petitioners claim that Joseph F. Whelan's birth defects were caused by his mother's ingestion during pregnancy of Bendectin. Bendectin is a prescription drug manufactured by Merrell for the treatment of morning sickness during pregnancy.

2. In May 1987, the district court granted petitioners' motion to stay this case pending a decision by the D.C. Circuit in another Bendectin case, *Richardson* v. *Richardson-Merrell, Inc.*, 857 F.2d 823 (D.C. Cir. 1988),

cert. denied, 493 U.S. 882 (1989). In September 1988, the D.C. Circuit issued its decision in *Richardson*, finding that with respect to "the oft-asserted claim of causal relationship between Bendectin and birth defects, the drug has been extensively studied and a wealth of published epidemiological data has been amassed, none of which has concluded that the drug is teratogenic."[1] *Richardson*, 857 F.2d at 832.

3. After the *Richardson* decision, the district court in this case issued a Show Cause Order requiring petitioners to "identify specific, admissible expert evidence that they would adduce at trial and that would satisfy their burden on the causation issue in this case, under the requirements of *Richardson* * * *." Pet. App. 12a-13a.

4. The only evidence that petitioners identified in response to the Show Cause Order consisted of four epidemiological studies. The four studies, which were published between 1979 and 1984, were not new. In fact, they were part of the record considered by the D.C. Circuit in *Richardson* and, accordingly, are part of the "overwhelming body" of epidemiological evidence that formed the basis of the *Richardson* decision. *Richardson*, 857 F.2d at 830.

5. In another Bendectin case decided in March 1990, the D.C. Circuit reaffirmed "the binding rule [of law] articulated in *Richardson*," that is, that in absence of some new methodology or evidence different from that considered and rejected in *Richardson*, "an expert opinion that Bendectin is a human teratogen which caused the plaintiff's birth defects is without scientific foundation under Federal Rule of Evidence 703 in the face of 'a wealth of published epidemiological data' to the contrary." *Ealy* v. *Richardson-Merrell, Inc.*, 897 F.2d 1159, 1160 (D.C. Cir.) (quoting *Richardson*, 857 F.2d at 832), *cert. denied*, 498 U.S. 950 (1990).

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[1] A "teratogen" is an agent or factor that causes the production of physical defects in a developing embryo. *Dorland's Illustrated Medical Dictionary* 1669 (28th ed. 1994).

6. In its August 30, 1990 Memorandum Order, the district court dismissed petitioners' claims with prejudice. Pet. App. 11a. In reaching its decision, the district court explained that in responding to the Show Cause Order it was "incumbent upon plaintiffs to demonstrate pursuant to *Richardson* and *Ealy* admissible scientific evidence upon which a jury could reasonably conclude that Bendectin causes [sic] Joseph's birth defects." *Id.* However, because the only evidence that petitioners had identified was four old studies that were part of the *Richardson* record, the district court found that petitioners had "not made the requisite showing" and, therefore, could not proceed to trial. *Id.*

7. In its decision, the district court also rejected petitioners' argument that the holdings of *Richardson* and *Ealy* are limited to Bendectin cases involving limb defects. Specifically, the district court explained that in *Richardson* the D.C. Circuit "carefully took pains to note that it had reviewed the record, including the wealth of published reports on Bendectin, and that *no credible and admissible scientific evidence exists that would establish the drug as a human teratogen.*" *Id.* 9a (emphasis supplied). Thus, "there is nothing implicit or explicit that restricts the holding of *Richardson* and *Ealy* solely to limb defects" because "[b]oth cases discuss more broadly the question of whether Bendectin is a human teratogen." *Id.* 9a-10a.

8. Petitioners filed a motion to vacate the district court's August 30 Memorandum Opinion, but in their motion they failed to present any new evidence or legal arguments. Instead, the only evidence that petitioners identified was the same four old epidemiological studies that the district court had rejected in its Memorandum Opinion. *See id.* 11a.

9. Before the district court decided petitioners' motion to vacate, the D.C. Circuit issued yet another Bendectin decision that reaffirmed the *Richardson* and *Ealy* holdings. *Raynor* v. *Merrell Pharmaceuticals Inc.*, 104 F.3d 1371, 1374 (D.C. Cir. 1997) ("[i]f we were to consider this

case under Rule 703, nothing would compel us to deviate from our holding in *Richardson*"). In the *Raynor* decision, the D.C. Circuit also held that the plaintiffs' expert evidence in that case was likewise inadmissible under Federal Rule of Evidence 702, under the factors announced in *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 509 U.S. 579 (1993). *See Raynor*, 104 F.3d at 1374-1375.

10. In addition to its admissibility rulings, the *Raynor* court determined that "even if the [plaintiffs'] expert testimony were admissible under *Daubert*, it is unlikely that a jury could reasonably find it sufficient to show causation." 104 F.3d at 1376. In support of that determination, the court highlighted a recent Bendectin decision in which a District of Columbia Superior Court judge "provided an 82-page survey of Bendectin research, and concluded that Merrell had 'established, by clear and convincing evidence, that post-1983 evidence makes it clear that Bendectin *is not a human teratogen* and that "*all responsible scientific thought*" *agrees with this conclusion.*'" *Id.* (quoting *Oxendine* v. *Merrell Dow Pharmaceuticals Inc.*, No. 82-1245, 1996 WL 680992, at *33 (D.C. Super. Ct. Oct. 24, 1996)) (emphasis supplied).

11. In its September 9, 1997 Memorandum Order, the district court denied petitioners' motion to vacate the dismissal of their claims. Pet. App. 4a. Citing the *Raynor* decision, the district court concluded that petitioners had failed to show any "intervening change in controlling law, previously unavailable evidence, or a need to correct a clear legal error or manifest injustice." *Id.*

12. Petitioners appealed the district court's rulings to the D.C. Circuit. In its Order granting Merrell's motion for summary affirmance, the D.C. Circuit explained that "[t]he merits of the parties' positions are so clear as to warrant summary action," and that "[e]ven if the evidence produced by [petitioners] in support of their claim were admissible, no reasonable jury could have found it suffi-

cient to establish causation." *Id.* 2a (citing *Raynor*, 104 F.3d at 1376-1377).

13. Petitioners' petition for rehearing and suggestion for rehearing *en banc* were both denied without recorded dissent. *Id.* 14a, 15a.

REASONS FOR DENYING THE WRIT

I. THE FACT-SPECIFIC BENDECTIN DECISION BELOW WAS CORRECTLY DECIDED, CONSISTENT WITH THIS COURT'S DECISION IN *DAUBERT* v. *MERRELL DOW PHARMACEUTICALS, INC.*

In this case, petitioners were directed by the district court back in 1988 to identify specific, admissible expert evidence other than that which had been rejected by the controlling precedent of *Richardson* that they would adduce at trial to satisfy their burden to show that Bendectin caused Joseph F. Whelan's birth defects. In the ten years since then, the *only* evidence that petitioners have ever identified consisted of four old published epidemiological studies that were part of the record in *Richardson* and, hence, part of the "wealth of published epidemiological data [that] has been amassed, none of which has concluded that the drug is teratogenic." *Richardson*, 857 F.2d at 832.

Because petitioners only identified four studies that were part of the evidence that had already been rejected by the court in *Richardson*, the district court properly determined that they had failed to identify any admissible scientific evidence upon which a jury could reasonably conclude that Bendectin was the cause of Joseph Whelan's birth defects. *See* Pet. App. 11a.

The district court likewise correctly denied petitioners' motion to vacate the dismissal of their claims. *See id.* 4a. By the time of the district court's denial of that motion, the D.C. Circuit had not only confirmed the controlling

precedent of *Richardson* and *Ealy*, but had also determined that a Bendectin plaintiffs' expert evidence failed to satisfy the admissibility requirements of *Daubert*. *See Raynor*, 104 F.3d at 1374-1375. Moreover, based on the current body of scientific evidence concerning Bendectin, the D.C. Circuit had already indicated that regardless of whether the plaintiffs' expert evidence were admissible, "it is unlikely that a jury could reasonably find it sufficient to show" that Bendectin causes birth defects. *See id.* at 1376. Accordingly, the district court in this case properly declined to reconsider the dismissal of petitioners' claims since there was no change in "controlling law, previously unavailable evidence, or a need to correct a clear legal error or manifest injustice." Pet. App. 4a (citing *Raynor*, 104 F.3d at 1376).

Under these circumstances, the D.C. Circuit's decision summarily affirming the dismissal of petitioners' claims was also correct. As that court specifically explained, the "merits of the parties' positions" in this Bendectin case "are * * * clear." *Id.* 2a. Even if the four epidemiological studies that petitioners identified in response to the Show Cause Order were admissible, "no reasonable jury could have found" that those four studies alone were "sufficient to establish" that Bendectin in fact caused Joseph Whelan's particular birth defects. *Id.* (citing *Raynor*, 104 F.3d at 1376-1377).

The summary affirmance by the D.C. Circuit in this case is entirely consistent with the *Daubert* decision. In *Daubert*, this Court set forth standards under Fed. R. Evid. 702 concerning the admissibility of certain expert evidence. *See* 509 U.S. 589-596. In doing so, however, the Court emphasized that "in the event that the trial court concludes that the scintilla of evidence presented [by one party] supporting a position is insufficient to allow a reasonable juror to conclude that the position more likely than not is true," the court should enter judgment as a matter of law in favor of the other party. *Id.* at 596. As examples of such cases, the Court cited

two Bendectin cases from the Fifth and Sixth Circuits, in which the courts had held that the plaintiffs' evidence was insufficient as a matter of law. *Id.* (citing *Turpin* v. *Merrell Dow Pharmaceuticals, Inc.*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990)).

II. THERE IS NO CONFLICT AMONG THE CIRCUITS

In addition to being consistent with *Daubert*, the decision below is also consistent with the holdings of the final decisions of every other federal appellate court which has considered a Bendectin case.

The federal appellate courts that have considered such issues in Bendectin cases have held either that the plaintiffs' evidence is inadmissible or that it is insufficient as a matter of law to prove causation. Thus, in addition to the D.C. Circuit in *Richardson* and *Ealy*, the Third and Ninth Circuits have found plaintiffs' Bendectin evidence to be inadmissible. *See, e.g., DeLuca* v. *Merrell Dow Pharmaceuticals, Inc.*, 791 F. Supp. 1042 (D.N.J. 1992), *aff'd without op.*, 6 F.3d 778 (3d Cir. 1993), *cert. denied*, 510 U.S. 1044 (1994); *Daubert* v. *Merrell Dow Pharmaceuticals, Inc.*, 43 F.3d 1311 (9th Cir.), *cert. denied*, 516 U.S. 869 (1995). And, in addition to the D.C. Circuit in *Raynor*, the First, Fifth, Sixth, and Tenth Circuits have affirmed that plaintiffs' Bendectin evidence is not sufficient to prove causation. *See, e.g., Elkins* v. *Richardson-Merrell, Inc.*, 8 F.3d 1068 (6th Cir. 1993), *cert. denied*, 510 U.S. 1193 (1994); *Wilson* v. *Merrell Dow Pharmaceuticals Inc.*, 893 F.2d 1149, 1154-1155 (10th Cir. 1990); *Brock* v. *Merrell Dow Pharmaceuticals, Inc.*, 874 F.2d 307, *modified*, 884 F.2d 166 (5th Cir. 1989), *cert. denied*, 494 U.S. 1046 (1990); *Turpin* v. *Merrell Dow Pharmaceuticals Inc.*, 736 F. Supp. 737 (E.D. Ky. 1990), *aff'd*, 959 F.2d 1349 (6th Cir.), *cert. denied*, 506 U.S. 826 (1992); *Lee* v. *Richardson-Merrell, Inc.*,

772 F. Supp. 1027 (W.D. Tenn. 1991), *aff'd without op.*, 961 F.2d 1577 (6th Cir.), *cert. denied*, 506 U.S. 868 (1992); *Lynch* v. *Merrell-National Laboratories*, 646 F. Supp. 856 (D. Mass. 1986), *aff'd*, 830 F.2d 1190 (1st Cir. 1987).

CONCLUSION

For the foregoing reasons, the petition should be denied.

Respectfully submitted,

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